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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/445,439	02/23/2000	BERNHARD A. SABEL	10644-0001-2	9939

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1940 DUKE STREET  
ALEXANDRIA, VA 22314

EXAMINER

HARTLEY, MICHAEL G

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 12/08/2003

36

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/445,439

**Applicant(s)**

SABEL ET AL.

**Examiner**

Michael G. Hartley

**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 101-122, 132 and 133 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 101-108, 111-122, 132 and 133 is/are rejected.
- 7) ☒ Claim(s) 109 and 110 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 35.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/15/2003 has been entered.

***Response to Amendment***

The amendment filed 8/15/2003 has been entered.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 101-108, 111-122, 132 and 133 are rejected under 35 U.S.C. 102(a) as being anticipated by Reszka (The Jour. of Pharmaco. and Exp. Therap., 1/1997, AW-PTO-1449).

Reszka discloses a method of preparing drug targeting system comprising preparing nanoparticles made of a polymer, wherein the method comprises polymerizing one or more monomeric units of said polymer (butylcyanoacrylate monomers), in the presence of a physiologically effective substance (the anticancer drug, mitoxantrone) and a stabilizer (poloxamer 188), see Materials and Methods section, page 233. The polymer, drug and stabilizer are within the scope of the claims. The drug loading is performed either before or after polymerization. Note: claims 116 and 118 do not specifically limit the drug in the nanoparticles, but only further define what is meant by "psychiatric disorders" in the Markush group of their respective base claims. The particles include <sup>14</sup>C labeled particles (see abstract), which are within the scope of claims 119 and 120, as this radionuclide is within

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the scope of substance for nuclear medicine, as radionuclides are capable of being detected by nuclear medicine techniques (note, the claims state "the diagnostic agent").

Claims 101-108, 111-118, 121, 122, 132 and 133 are rejected under 35 U.S.C. 102(b) as being anticipated by Beck (Jour. of Microencapsulation, 1993, PTO-892).

Beck discloses a method of preparing drug targeting system comprising preparing nanoparticles made of a polymer, wherein the method comprises polymerizing one or more monomeric units of said polymer (butylcyanoacrylate monomers), in the presence of a physiologically effective substance (the anticancer drug, mitroxastrone) and a stabilizer (poloxamer 188), see Materials and Methods section, page 103. The polymer, drug and stabilizer are within the scope of the claims. The drug loading is performed either before or after polymerization. Note: claims 116 and 118 do not specifically limit the drug in the nanoparticles, but only further define what is meant by "psychiatric disorders" in the Markush group of their respective base claims.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 101-108, 111-122, 132 and 133 are rejected under 35 U.S.C. 103(a) as being unpatentable over either one of Reszka (The Jour. of Pharmacol. and Exp. Therap., 1/1997, AW-PTO-1449) or Beck (Jour. of Microencapsulation, 1993, PTO-892) in view of Kreuter (WO 95/22963).

Reszka and Beck disclose a method of preparing drug targeting system comprising preparing nanoparticles made of a polymer, wherein the method comprises polymerizing one or more monomeric units of said polymer (butylcyanoacrylate monomers), in the presence of a physiologically effective substance (the anticancer drug, mitroxastrone) and a stabilizer (poloxamer 188), as set forth above.

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Reszka and Beck fail to disclose nanoparticles comprising all the same drugs as claimed.

Kreuter discloses drug nanoparticles and teaches that various drugs may be used interchangeably, in an equivalent manner, to gain the advantage of providing the desired therapeutic or diagnostic effect. The drugs include anticancer drugs, as disclosed by Reszka and Beck, as well as, drugs of nuclear medicine, antidepressants, etc., see page 11.

It would have been obvious to one of ordinary skill in the art to modify the drug nanoparticles disclosed by Reszka and Beck to include the various drugs as claimed, because it is well known in the art that various drugs, such as those claimed, may be used in an equivalent manner in such nanoparticles to gain the advantage of providing a desired therapeutic or diagnostic effect for the particles, as shown by Kreuter.

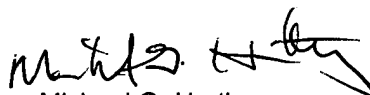
***Allowable Subject Matter***

Claims 109 and 110 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art fails to specifically teach or suggest the use of the particular stabilizers recited in claims 109 and 110 in methods of preparing surfactant free polymer drug nanoparticles as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
Michael G. Hartley  
Primary Examiner  
Art Unit 1616

MH  
11/24/2003